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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
STEADMAN, DAVID J	

ART UNIT	PAPER NUMBER
1656	

DATE MAILED: 02/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/652,928	CHIAUR ET AL.	
	Examiner	Art Unit	
	David J. Steadman	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-28 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-28 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

[1] The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1656.

[2] Claims 1-28 are pending in the application.

[3] Applicant's claim to domestic priority in the first paragraph of the specification is acknowledged. In response to this Office action, applicant should amend the priority claim to include the status of the parent application, application 09/385,219.

Election/Restrictions

[4] Claims 1 and 4 link(s) inventions I and II. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 1 and 4. Claims 7 and 14 link(s) inventions III-X. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 7 and 14. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.

Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

[5] Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 2 and 5, drawn to a method for screening compounds that modulate Fbp1-related disorders by measuring the interaction of Fbp1 with Fbp5, classified in class 435, subclass 7.1.

II. Claims 3 and 6, drawn to a method for screening compounds that modulate Fbp1-related disorders by measuring the levels of Fbp5 protein, classified in class 435, subclass 7.1.

III. Claims 8 and 10, drawn to a method for screening comprising contacting a cell and β-catenin and detecting a change in the interaction of Fbp1 or βTrcp2 with β-catenin, classified in class 435, subclass 7.1.

IV. Claims 8 and 11, drawn to a method for screening comprising contacting a cell and β-catenin and detecting a change in the interaction of Fbp1 or βTrcp2 with IkBα, classified in class 435, subclass 7.1.

V. Claims 8, 12, and 15, drawn to a method for screening comprising contacting a cell and β-catenin and detecting a change in the levels of β-catenin protein, classified in class 435, subclass 7.1.

VI. Claims 8, 13, and 16, drawn to a method for screening comprising contacting a cell and β-catenin and detecting a change in the levels of IkBα protein, classified in class 435, subclass 7.1.

VII. Claims 9 and 10, drawn to a method for screening comprising contacting a cell and IkBα and detecting a change in the interaction of Fbp1 or βTrcp2 with β-catenin, classified in class 435, subclass 7.1.

VIII. Claims 9 and 11, drawn to a method for screening comprising contacting a cell and IkBα and detecting a change in the interaction of Fbp1 or βTrcp2 with IkBα, classified in class 435, subclass 7.1.

IX. Claims 9, 12, and 15, drawn to a method for screening comprising contacting a cell and IkBα and detecting a change in the levels of β-catenin protein, classified in class 435, subclass 7.1.

X. Claims 9, 13, and 16, drawn to a method for screening comprising contacting a cell and IkBα and detecting a change in the levels of IkBα protein, classified in class 435, subclass 7.1.

XI. Claims 17-19 and 22-28, drawn to a method for diagnosing decreased fertility and a method for detecting an Fbp1-related infertility disorder, classified in class 435, subclass 6.

XII. Claim 20, drawn to a pharmaceutical composition, classified in class 514, subclass 789.

XIII. Claim 21, drawn to a method of treating Fbp1-related infertility, classified in class 514, subclass 789.

[6] The inventions are distinct, each from the other because:

[7] The methods of Groups I-XI and XIII are unrelated as they comprise different method steps, utilize different products, and/or yield different results.

[8] The pharmaceutical composition of Group XII is unrelated to the methods of Groups I-XI as it is neither made nor used by the methods of Groups I-XI.

[9] The pharmaceutical composition of Group XII and the method of Group XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the pharmaceutical composition of Group XII can be used in the methods of Groups I-X.

[10] MPEP § 803 sets forth two criteria for a proper restriction between patentably distinct inventions: (A) The inventions must be independent or distinct as claimed and (B) There must be a serious burden on the examiner. As shown above, the inventions of Groups I-XIII are independent or distinct, thus satisfying the first criterion for a proper restriction. MPEP § 803 additionally states that a serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation either separate

classification, separate status in the art, or a different field of search. Each of the inventions listed as Groups I-XIII requires a separate patent and non-patent literature search. As such, co-examination of the inventions of Groups I-XIII would require a serious burden on the examiner.

[11] Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

[12] Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Rejoinder

[13] The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.

Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Steadman whose telephone number is 571-272-0942. The examiner can normally be reached on Mon to Thurs, 6:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David J. Steadman, Ph.D.
Primary Examiner
Art Unit 1656